



BUTYLATE FACTS

Introduction

The Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996 requires EPA to review all the tolerances for registered chemicals in effect on or before the date of enactment of FQPA. In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a revocation occurs. A reregistration eligibility decision (RED) for butylate was completed in September 1993, prior to FQPA enactment; therefore, it needed to be updated to consider the provisions of the Act. The Agency's report on the FQPA tolerance reassessment progress and interim risk management decision for butylate included a review of dietary exposure, including food and drinking water sources. The report indicates that butylate, by itself, poses no risk concerns within the limits of the existing tolerances; therefore, no risk mitigation is needed, and no further actions are warranted at this time. The existing butylate tolerances remain in effect, until such time as a determination of whether a full reassessment of the cumulative risk from thiocarbamate pesticides, including butylate, may be needed and is completed.

Use Profile

Butylate is a selective herbicide for use on field corn, sweet corn, and popcorn to control grassy and broadleaf weeds and nutsedge, and is formulated as a liquid emulsifiable concentrate (85.1% active ingredient). The chemical is applied by ground equipment, either broadcast or band (includes boom sprayer; soil injection equipment; and center pivot irrigation), and is immediately incorporated into the soil. Butylate may be applied preplant, at plant, postplant, and after harvest (fall) at a maximum application rate of 6.3 pounds of active ingredient per acre (lbs a.i./A).

Regulatory History

Butylate was first registered as a pesticide in the U.S. in 1967. EPA issued a Data Call-In (DCI) Notice in 1981, and a Registration Standard in September 1983 (PB85-147304), which required product chemistry, toxicology, ecological effects and environmental fate data. The Agency issued a second DCI in October 1990, requiring additional product chemistry, ecotoxicity, toxicology, environmental fate, residue chemistry and exposure data. Based on this information, a reregistration eligibility decision (RED) for butylate was completed in September 1993.

Human Health Assessment

EPA assessed dietary risk posed by butylate use. Deterministic Tier I analyses were conducted using tolerance level residues and 100% crop treated parameters with the Dietary Exposure Evaluation Model (DEEM™) to assess both acute and chronic dietary (food) risks. Estimated dietary (food) exposure for all population subgroups, including infants and children, are very low and not of concern to the Agency. Additionally, there is no acute or chronic concern of drinking water exposure to butylate from surface or ground water sources, based on Tier I modeling. Because of the chemical's high volatilization and use practice of soil incorporation, significant residues of butylate are not expected to reach ground or surface water. Therefore, no risk mitigation measures are necessary to address dietary risks of butylate use.

Aggregate risk looks at the combined risk from exposure through food, drinking water, and residential uses. For butylate, the aggregate risks are limited to food and water exposure, because there are no residential uses. The aggregate (food + drinking water) risks for both acute and chronic exposure are very low and not of concern to the Agency; therefore, no risk mitigation measures are necessary to address aggregate risks of butylate use.

Tolerances

Tolerances are established for residues of butylate (S-ethyl diisobutylthiocarbamate) in/on raw agricultural commodities as defined in 40 CFR 180.232. Because there is no reasonable expectation of finite residues in meat, milk, poultry, and eggs, tolerances for residues of butylate in meat, milk, poultry, and eggs are not required. Based on the residue data submitted, the established tolerances for butylate remain in effect at 0.1 ppm for all registered commodities, until such time as a determination of whether a full reassessment of the cumulative risk from thiocarbamates pesticides, such as butylate, may be needed and is completed.

Cumulative Risk

FFDCA, as amended, requires that the Agency, when considering whether to establish, modify, or revoke a tolerance, consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency is currently examining whether and to what extent thiocarbamates pesticides may share a common mechanism of toxicity. Preliminary determinations indicate that the potential to produce a common toxic effect, neuropathy (e.g., degeneration and demyelination of the sciatic nerve), and the similarities in structure and metabolism, may support grouping of the thiocarbamates based on their ability to produce a common effect by a common mechanism. Assuming these assertions are correct, preliminary screening-level chronic cumulative dietary food risk analyses do not provide evidence that cumulative exposure of the human population, including infants and children, to the neuropathic thiocarbamates would raise concern of adversely affecting human health.

The preliminary determination of whether and to what extent thiocarbamates pesticides may share a common mechanism of toxicity, and accompanying screening-level cumulative dietary analyses are to be presented to the FIFRA Science Advisory Panel for peer review on September 7, 2001. Pending their review of the information, the Agency expects to complete the cumulative risk assessment for thiocarbamate pesticides, at which time, provided the risk analyses concludes chronic cumulative dietary risks are not of concern to the Agency, the butylate tolerances will be considered reassessed, in accordance with FFDCA, as amended.

For More Information

You may obtain electronic copies of the Agency's report on FQPA tolerance reassessment progress and interim risk management decision for butylate from the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. In addition, copies of documents related to the Agency's decision on butylate that have been released to the public may also be accessed at <http://www.epa.gov/pesticides/reregistration/status.htm>. The Agency has also established an official record for this action under docket control numbers OPP-34246. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

For more information about EPA's pesticide reregistration program or the Agency's report on FQPA tolerance reassessment progress and interim risk management decision for butylate, please contact the US EPA, OPP, Special Review and Reregistration Division (7508C), Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is <http://ace.orst.edu/info/nptn/>.